Contract NASW-2645

CR-144350

MARKET STUDY:

BIOLOGICAL ISOLATION GARMENT

Prepared for:

National Aeronautics and Space Administration
Technology Utilization Office
Washington, D.C. 20546

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May, 1975

1. Report No. CR - 144350	2. Government Accession No.	3. Recipient's Catalog No.
4. Title and Subtitle BIOLOGICAL ISOLATION GARMENT: A Market Study		5. Report Date 6. Performing Organization Code
7. Author(s) - - - - - -		8. Performing Organization Report No. 10. Work Unit No.
9. Performing Organization Name and Address Techno/Economic Studies Group IIT Research Institute 10 West 25th Street Chicago, Illinois 60616		11. Contract or Grant No. NASW - 2645
12. Sponsoring Agency Name and Address National Aeronautics and Space Administration Washington, D.C. 20546		13. Type of Report and Period Covered Market Study 14. Sponsoring Agency Code KT
15. Supplementary Notes		

16. Abstract

The Biological Isolation Garment was originally designed for Apollo astronauts to wear upon their return to Earth from the Moon to avoid the possibility of their contaminating the environment. The concept has been adapted for medical use to protect certain patients from environmental contamination and the risk of infection.

The market study focuses on the nature and size of the anticipated market with certain findings and conclusions relative to clinical acceptability and potential commercial viability of the Biological Isolation Garment.

17. Key Words (Suggested by Author(s))	18. Distribution Statement
	Unclassified - Unlimited

19. Security Classif. (of this report)	20. Security Classif. (of this page)	21. No. of Pages	22. Price*
Unclassfied	Unclassified	16	

*For sale by the National Technical Information Service, Springfield, Virginia 22151

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1. INTRODUCTION

The primary objective of this market study was to provide in-depth field findings relative to the market potential of the Biological Isolation Garment (BIG). Discussion on the following pages focuses on the nature and size of the anticipated market, analysis of clinical acceptability and commercial potential and conclusions and recommendations.

2. BACKGROUND

2.1 Product Description

The Biological Isolation Garment was originally designed for the Apollo Astronauts to wear upon return to earth to avoid the possibility of their contaminating the environment. The concept was then adapted for medical use to protect certain patients from environmental contamination and the risk of infection. A prototype garment was developed and has been tested in clinical use by the National Cancer Institute with favorable results.

The BIG consists of a coverall type suit with attached mittens and slippers, all made with a penetration resistant fabric, "BAR-BAC". The fabric prevents penetration of particles of greater than 0.3 microns in diameter. A separate hood with a transparent face mask is attached to the suit. The entire garment is easily sterilized. Air is supplied through a diffuser at the top of the head; a flexible tube conducts conducts the purified air from the filter/blower to the head piece. The filter/blower system consists of a replaceable HEPA (high efficiency particulate air) filter cartridge unit powered by rechargable batteries and a blower motor. Particles of greater than 0.3 microns in diameter are filtered with 99.997% accuracy. Positive pressure is maintained in order to prevent entry of unfiltered air into the suit.

The filter system weighs 5.5 pounds; the blower motor weighs 0.43 pounds. A manual blower system is provided in the event of power system failure.

It is anticipated that the BIG could be sold commercially for approximately $1000 to $2000, depending on production quantities and possible design variables.

2.2 Nature of Use Biological Isolation Garment

The scope of this study was limited to medical applications in which a patient is subject to a high degree of risk of infection from the normal hospital environment, either as a result of a disease itself or treatment of a disease. For these applications, the Biological Isolation Garment must be used in conjunction with a stationary sterile environment such as a laminar air flow patient isolator. The BIG then becomes an extension of the controlled environment, allowing patients to leave the confines of the isolation unit while still being maintained in a controlled environment. Egress from the isolator may be required for treatment in other parts of the hospital (i.e., x-ray, radiotherapy). In addition, the BIG would enable a patient to more closely interact with visitors or simply break the monotony of isolation, factors which may be very important for patients psychologically less able to tolerate an extended period of isolation.

In summary, the BIG in its present design is an adjunct to a patient isolation system and as such, has no clinical application other than as an extension of a protected environment. Thus, in order to determine the commercial potential of the BIG, nature and extent of use of patient isolators must first be assessed.

Patient Isolators

The term patient isolator, a facility in which a patient is protected from the hospital environment, generally refers to a controlled environment in which the air supply is received through HEPA filters. Most have laminar air flow, where the entire body of air within the confined space moves with uniform velocity over parallel flow lines. The basic protective capability of this concept is the fact that airborne organisms cannot migrate against an air flow. The incoming air flow is filtered by means of HEPA filters, ensuring protection against organisms of greater than 0.3 micron in diameter. The patient care area is maintained at a slightly higher pressure; any air leakage is thus outward rather than inward. A nearly sterile environment is maintained by:

- Thorough cleaning of units before they are reoccupied
- Patients must undergo extensive decontamination procedures prior to isolation
- All equipment and material entering the room must be sterilized.
- Procedure or method to allow medical staff access to patient without contaminating the environment

Laminar flow rooms have been used for patient care for over six years; operating room facilities have been in existance for nearly 10 years. Laminar flow and ultra-clean facilities are also used in industry; however, these applications are beyond the scope of the study. Both portable and stationary laminar air flow rooms are commercially available; designs are available for use in existing single hospital rooms and wards. Most are single patient units, although multiple bed units are available.

Laminar flow facilities range in price from $5,000 to $30,000 depending on ancillary equipment, size, configuration, etc. The significant cost of the isolators is, however, operating rather than acquisition cost. In a 1972 study conducted by Arthur D. Little, Inc. for the National Cancer Institute, it was estimated that the operating cost for one research unit studied was approximately $800 per patient day. In a four-bed laminar flow unit, costs were estimated at $200 to $300 additional per patient day over the cost of conventional hospital rooms.

Typical clinical applications for patient isolators include:

- Chemotherapy/leukemia treatment
- Transplantation
- Burns
- Radiation injury
- Immune disease
- Intensive care units
- Respiratory disease
- Pediatric isolation

The clinical objective in reverse isolation is to protect hospital patients who are highly vulnerable to infection from the environment. This is a very severe problem for certain patients: for example, infectious complications are responsible for nearly 70% of all deaths in acute leukemia. This susceptibility may be caused by a number of factors, for example:

- Administration of immuno-suppressive drugs as in organ or marrow transplants or for patients with acute leukemia
- Impairment of natural immunity and/or bone marrow function as in intensive chemotherapy and radiation injury

- Consequence of condition itself, as combined immune deficiency and aplastic anemia
- Result of severe trauma, as with burns or extensive surgery.

Where impairment of natural immunity is induced as part of a treatment protocol as in chemotherapy or transplantation, evidence indicates that reverse isolation may enable the physician to administer more therapeutic agents while still not significantly increasing risk of infection, a usual complicating factor of such treatment.

Although the reverse isolation facilities for patient care have been in hospital use for a significant period of time, many authorities still consider them to be at the experiemental or research stage. Their benefit and efficacy is still a point of controversy. Isolation in a bacteria free environment may be a significant contribution to the health care needs of certain hospital patients or it may provide little or no substantial benefit. For example, the conclusion of a recent study of this issue concluded that while laminar air flow facilities are a promising research tool and the evidence is clear that their use can reduce morbidity and mortality, the ultimate utility of isolation rooms in enhancing long term survival for a significant number of patients has not been established.*

Surgical or operating room units have received more widespread acceptance; use is especially prevalent for orthopedic surgical procedures such as total hip replacement. It is estimated that there are approximately 1500 operating room units currently in use.

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* E. Drazen, A. Levine, "Laminar Air flow Rooms", Hospitals Vol. 48, Jan. 1, 1974.

2.3 Market Need/Acceptance

In general, the medical community tends to be slow in adopting new items of technology unless the advantages and benefits are very clearly demonstrated. The benefits of reverse isolation apparently have not been proven beyond doubt, and therefore the probability of widespread adoption in the near term is uncertain.

The benefits and advantages of the BIG, a complementary device must thus be clearly demonstrated as well. If reverse isolation becomes a common treatment method, clinical acceptance and use of the BIG will then depend upon factors such as the following:

- Advantage over current practice
- Benefits in terms of expanded treatment possibilities
- Acceptance of garment's reliability
- Patient attitudes towards wearing the garment
- Anticipated frequency of use
- Price and operating/maintenance cost

3. SIZE OF THE MARKET

3.1 Patient Isolators

In order to determine the commercial potential of the Biological Isolation Garment, the current and future extent of use of patient care laminar flow rooms will be assessed.

Based on available data, we estimate that approximately 160 to 200 laminar flow patient isolators have been purchased for domestic use to date. Slightly less than half have been purchased by U.S. Cancer Centers; the remainder are in general and other government hospitals. Of the seventeen cancer centers,

twelve are reported to have patient isolator units, an average of over five units per center. However, M.D. Anderson (University of Texas), one of the original cancer centers, reportedly has 26 units; if this is discounted, the average per cancer center drops to approximately three to four. Hospitals other than cancer centers have an average of two units each. Overall, our research indicates that nearly half of the total units are used primarily for chemotherapy/acute leukemia treatment.

The adoption of patient isolators has been slow. Moreover, purchases by general and other hospitals appears to be diminishing: only 1/3 of the total were purchased after 1972. U.S. cancer centers, however, have increased their acquisition of units over the last three years.

The market for patient isolators is dominated by three suppliers, who account for over 75% of sales. Several firms who supplied units in the past have gone out of business or have eliminated or de-emphasized hospital sales. The market has been difficult to develop and expand because of factors such as:

- Large research expense associated with manufacturing
- High cost of sales to a geographically disbursed market
- Long sales lead time
- Medical community tend to regard isolation units as a research item

3.2 Biological Isolation Garment

The maximum size of the current market for the Biological Isolation Garment for medical use is limited to the patient isolation facilities currently in place (assuming that they are utilized). One garment would be required per patient unit, since the garment can be sterilized between patients.

The current market for the Biological Isolation Garment is thus 160-200 units, the number of patient isolators in place (the majority are one patient facilities). At an estimated sales price of $1000 to $2000 per garment, the maximum current market is approximately $160,000 to $400,000. Since the BIG has been successfully tested in clinical use, it is likely that adoption of the garment may be relatively rapid, at minimum an estimated one garment per hospital, or approximately 60 units within one to two years after commercialization.

Future sales potential could expand considerably if the patient isolation concept is accepted as standard practice by the medical community. It is virtually impossible to predict when this will occur.

4. COMPETITIVE ENVIRONMENT AND CHANNELS OF DISTRIBUTION

4.1 Competitive Environment

During the course of our research, we identified no commercially available products to provide a mobile sterile environment for patients confined to isolator units. If it is necessary to remove the patient from the isolator, (for example, for treatment in another part of the hospital) current practice is to dress the patient in a sterile surgical gown and mask in order to minimize risk of infection. Alternatively, the problem is often circumvented by bringing portable equipment which has been decontaminated into the isolator.

4.2 Channels of Distribution

The most appropriate channel of distribution for the BIG would be direct sales contact either through a company sales force or through distributors with established hospital contacts. Direct sales contact is commonly used for patient

isolators, and since the items are complementary, greatest sales success would likely be achieved if sold together.

5. COMMERCIAL POTENTIAL

5.1 Market Penetration

Approximately one to two years would be required for a new company to develop the necessary sales and manufacturing capabilities to produce and commercialize the Biological Isolation Garment. This time could possibly be reduced, howevever, by a company adding the BIG to an existing line of patient isolators or hospital products.

Assuming that more widespread adoption of patient isolators occurs, expected sales of the BIG would also depend upon factors such as the following:

- Magnitude of sales effort
- Price at which the BIG can be sold
- Operation and maintenance cost
- Patient acceptance of BIG
- Development of non-medical applications

5.2 Price/Performance Impact

The sales price of the Biological Isolation Garment is difficult to specify at this time, but it is anticipated that it could be sold for approximately $1000 to $2000 depending on design and production variables. Price/performance impact must thus be assessed in terms of the incremental benefit of the BIG to treatment of certain hospital patients. Several manufacturers of patient isolators felt that the market is very cost sensitive, and price would be very important, especially when reverse isolation units are in use less than

half of the time.

5.3 Anticipated Market Barriers

The primary factors which we foresee as potentially affecting market acceptance of the Biological Isolation Garment (assuming acceptance of patient isolators) are:

- Present practices may be considered satisfactory
- Patient rejection of bulky suit

The primary means overcoming barriers to acceptance is demonstration and wide dissemination of clinical test results and anticipated benefits of the garment. The medical community must first accept the fact that the BIG offers significantly greater protection than present practices and that it would be a useful addition to patient care. Similarly, any objections which a patient may have to the appearance and comfort of the garment would be minimized or eliminated if it is demonstrated that risk of infection is reduced or possible activities expanded.

5.4 Interested Manufacturers

Seven firms have expressed interest in performing a detailed evaluation of the Biological Isolation Garment to explore manufacturing and sales possibilities. Four firms are manufacturers of patient isolators; the remainder manufacture and distribute other hospital supplies and equipment. The following is a list of interested companies, along with the name of the primary contact and relevant products.

Company	Contact	Product
Angelica Uniform Company St. Louis, Mo.	Hal Pohle Director of Hospital Mktg.	"BAR-BAC" Fabric
Envirco Corp. Albuquerque, NM.	Lou Sanders General Sales Manager	Laminar flow isolation rooms and surgical isolators
Environmental General Corp. Alexandria, Va.	Gabriel Danch President	Laminar flow patient environment
Sci-Med Environmental Systems, Inc. Minneapolis, Minn.	Paul D. Pederson, Jr. Vice President	Laminar flow patient isolation system
G.D. Searle Skokie, Illinois	Wellman Hoff Corporate Research	Diversified health care products
Stackhouse Associates Manhatten Beach, Ca.	Wyman Stackhouse President	"Bio-vak" surgical mask system
Weber Technical Products, Inc. Lunenburg, Mass.	Al Dettenreider Manager, Medical Products	Patient and surgical isolators

5.5 Patent Status

A patent on the Biological Isolation Garment, author by F.R. Spross, has been issued to NASA. Patent number 3,516,404 describing "contamination proof wearing apparel" was issued in 1970.

6. CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

The following conclusions are made on the basis of our market study:

- The BIG is potentially a useful and beneficial addition to the health care requirements of certain hospital patients
- There are no competitive products available; current practice includes using a surgical gown and mask outside the isolator or circumventing the problem by bringing decontaminated portable equipment into the isolator.
- The BIG has been successfully tested in clinical use by the National Cancer Institute
- The BIG must be used in conjunction with a patient isolator, as a means of extending the controlled environment beyond the isolation room
- The commercial potential of the BIG depends on the rate of adoption and use of patient isolators
- Adoption and use of patient isolators has been slow and there is still some degree of doubt as to their benefit; however, acceptance of innovations by the medical community is typically slow unless there is a very clear demonstration of benefits.
- There are approximately 160 to 200 patient isolation units in use, representing the maximum current market for the BIG.
- This limited sales potential must be weighed against anticipated benefits to certain patients

6.2 Recommendations

- The BIG would have the greatest likelihood of commercial success if sold in conjunction with patient isolators or other hospital supplies, for the following reasons:
  - Sales channels already developed

  - R&D expense may be lower
  - Limited market to support profitability

- NASA should consider the possibility of granting an exclusive license on the technology as an incentive for a firm to commit the required manufacturing and sales development funds.
- Additional prototype units should be developed for further clinical evaluation and wide dissemination of test results.
- Industrial and other medical applications for the garment should be explored, for example:
  - Use in sterile manufacturing processes, such as pharmaceuticals and electronics
  - Use as a protective garment for certain industrial accidents
  - Modification of design for use by sterile operating room personnel
- Promote and possibly support the involvement of interested manufacturers in any necessary product refinement and commercial development effort.
- Wide dissemination of clinical test results is vital to attain favorable exposure in the medical community.